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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,519	05/01/2001	Ralf M. Luche	200125.422	4032

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EXAMINER	
NASHED, NASHAAT T	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/847,519	Luche et al.
Examiner	**Art Unit**
Nashaat T. Nashed	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 6, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *3-14* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3-14* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *9*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The application has been amended as requested in the communication filed August 6, 2002. Accordingly, claims 1, 2, and 15-49 have been canceled and claims 4, 6 and 11 have been amended.

Claims 3-14 are pending and under consideration.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth in the prior Office action, paper number 8.

Claims 3-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In response to the above rejections, Applicants argue that the prior Office action has not set forth a *prima facie* case showing that the subject matter of the instant claims, i. e., polynucleotide encoding a Dual Specificity Phosphatase-14 (DSP-14) polypeptide lacks utility.

Applicants' arguments filed 8/6/02 have been fully considered but they are not deemed to be persuasive. The examiner disagrees with applicants' arguments. The previous Office action sets out a *prima facie* case of lack utility, explaining by sound scientific reasoning and support from the art why a person of ordinary skill in the art would doubt that the asserted and specific utility of the amino acid sequence of SEQ ID NO: 2. Applicants have presented no evidence or, indeed, any arguments to establish that the specification established both a well established and substantial utility. Applicants merely identify several statements in the specification which have been considered by the

examiner and assert that "one of ordinary skill in the art would know the uses of DSP-14". Applicants make no effort to explain why they consider the disclosure of some "conserved fragment" is sufficient to establish a specific and substantial utility. Applicants assertions that both U. S. Patent 6,258,582 (582) and 6,132,964 (964) support their asserted utility, and the phospholipase disclosed by Acton in U. S. Patent 6,268,135 (135) has not been demonstrated to have a phospholipase activity are misplaced. The 135 patent is an issued patent and therefore, it is presumed to be valid under 35 U. S. C. § 282. Applicants is reminded that they have not demonstrated any kind of catalytic activity of any kind for the polypeptide of SEQ ID NO: 2. Since the phospholipase utility for the protein in the 135 patent is presumed to be a credible utility, the argument set forth in the prior Office action remains valid. With regard to the 582 and 964, the application identified duel specificity phosphatase as a distinct family of enzymes from those of Ser/Thr-phosphatase and Tyr-phosphatases. Thus, the presence of the homologous domains in other enzymes is not sufficient diagnostic feature for a specific family of enzymes. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

As indicated in the prior Office action, paper number 8, even if the duel specificity phosphatase asserted utility is accepted, the specification does not contain a specific or a substantial utility for the polypeptide of SEQ ID NO: 2. It is said that the claimed nucleic acid encodes real-world use, i. e., duel specificity phosphatase that play a role in regulation of MAP-kinase signal transduction cascade. MAP kinases are a family of enzymes each of which has a specific function and is regulated by specific sets of enzymes inncluding duel specificity phosphatase. The application fails to identify a specific MAP-kinase that is regulated by the polypeptide of SEQ ID NO: 2 or any specific disease in which the polypeptide plays a role. Thus, even if the asserted doubtful duel specificity phosphatase is accepted generic utility, the application failes to identify an specific and substantial utility for the polypeptide of SEQ ID NO: 2, and hence, the nucleic acid encoding said polypeptide.

Claims 3-5 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the prior Office action for the reasons set forth in the prior Office action paper number 8.

Applicants argue that the claimed invention is fully described as specification reasonably conveys sufficient, detailed and relevant characteristics of the claimed polypeptides, and that a person skilled in the art would recognize that the applicants possessed the claimed invention at the time the application was filed.

Applicants' arguments filed 8/6/02 have been fully considered but they are not deemed to be persuasive. As the Applicants point out, the claimed invention directed to any polypeptide having 15 contagious amino acid residues of SEQ ID NO: 2 or hybridizes to SEQ ID NO: 1. The claims, however, are not limited to a specific function that has been identified and demonstrated in the specification. It is said "the instant application discloses the sequence and location of catalytic active site of the DSP-14". The "catalytic active site" of an enzyme refers to a three dimensional component of the three dimensional structure of the enzyme in which the substrate(s) are bound and a chemical reaction takes place. One of ordinary skill in the art would recognize that several parts of the polypeptide would contribute residue(s) to the catalytic active site. Since the application does not contain a three dimensional structure information for the polypeptide of SEQ ID NO: 2, neither the location or the sequence(s) involved in constructing the active site are known. What the applicants have disclosed is an a generic sequence of amino acid fragment contained within the polypeptide of SEQ ID NO: 2 which is conserved among some phosphatase. The claims are not limited to any functional activity or a specific structural features. As indicated above, SEQ ID NO: 3 is found in other enzymes which are not duel specificity phosphatase. Thus, SEQ ID NO: 3 is of no diagnostic value for the asserted utility by the applicants, and could be a part of the binding site for a phosphate group. Amending the claims to include functional activity would obviate these rejections.

Claims 3-14 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for any claims for the reasons set forth in the prior Office action, paper number 8.

Applicants argue that the specification fully enables a person skilled in the art to make and use the invention as claimed, and once again recite parts of the specification to support their arguments

Applicants' arguments filed 8/6/02 have been fully considered but they are not deemed to be persuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert the disclosure of the nucleic and amino acid sequences of SEQ ID NO: 1 and 2, respectively, and the various computer programs are sufficient enablement for the claims. Applicants make no effort to explain why they consider the disclosure of two sequences and methods of alignment are sufficient disclosure for the claimed invention. Applicants would like us believe they have

identified some utility for the polypeptide of SEQ ID NO: 2 based on the presence of SEQ ID NO: 3. The disclosed protein has very little sequence homology to any duel specificity phosphatase and have highest homology to a phospholipase which places the asserted utility in doubt, see above. Claim 3 is drawn to any polypeptide having any function and containing 15 contagious amino acid residues from SEQ ID NO: 2. Claim 6 is drawn to any nucleic acid having any function or encoding a polypeptide having any function which contains insertion, deletion, substitution and combination thereof mutants up to 25% of the amino acid residues. Claim 11 is drawn to any nucleic acid having any function which hybridizes under low to medium stringency to the nucleic acid sequence of SEQ ID NO: 1. The specification have not provided any teaching that would enable one of ordinary skill in the art to practice the full scope of the claimed invention of any of claims 3, 6 and 11 for the reasons set forth in the prior Office action, paper number 8. There is no three dimensional structure which may enable one of ordinary skill in the to identify a handful of amino acid residues of SEQ ID NO: 2 for mutations or all possible biological source which may have a nucleic acid that hybridizes to SEQ ID NO: 1 and have any function, let alone a polypeptide comprising only 15 contagious amino acid residues having any function from any biological source. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amended claim is drawn to 15 contiguous nucleotide (5 amino acids out of 220) of a nucleic acid encoding a protein which is 75% homologous to SEQ ID NO: 2. Thus, the claims encompasses embodiments which are unknown to one of ordinary skill in the art and could not be searched commensurate with the scope of the claim.

New Rejection:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another

filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-14 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 01/46394 [('394), see IDS, paper number 9].

The 394 teaches the nucleic acid sequence of SEQ ID NO: 5 which encodes the phosphatase of SEQ ID NO: 17. The nucleic acid sequence of SEQ ID NO: 5 of the 394 is 94% identical to the nucleic acid sequence of SEQ ID NO: 1 of the instant application and would be expected to hybridize to SEQ ID NO: 1 under the most stringent hybridization conditions. The open reading frame in SEQ ID NO: 17 is identical to the open reading frame in SEQ ID NO: 1 of the instant application. The amino acid of SEQ ID NO: 17 is identical to the amino acid sequence of SEQ ID NO: 2, except for residue number 85 which the examiner believe its an error in either SEQ ID NO: 14 of the 394 or SEQ ID NO: 2 of the instant application because the nucleic acid sequences are identical (claim 3, 6, and 11). Also, the 394 patent teach a vector (page 13, second paragraph), host cells (page 16, second paragraph), and a recombinant method to make polypeptide (page 19, paragraph 2-4), claims 4, 5, 7-10, and 12-14.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nashaat T. Nashed, Ph. D.
Primary Examiner